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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,020	06/20/2003	Andrea D. Branch	RII-003CPUSDV1	6838
959	7590	09/14/2006	EXAMINER BOESEN, AGNIESZKA	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			ART UNIT 1648	PAPER NUMBER

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/601,020

Applicant(s)

BRANCH ET AL.

Examiner

Agnieszka Boesen

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/20/05, 12/05/03.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received June 26, 2006.

Election/Restrictions

Applicant's election with traverse of group I, claims 49-89, SEQ ID NO: 1 and SEQ ID NO: 4 is acknowledged. Applicant argues that the generic claim 49 embraces the use of HCV alternate reading frame polypeptides, and that SEQ ID NOs: 3, 4, 5, and 6 are all contained within SEQ ID NO: 2, and that SEQ ID NO: 9 shares approximately 77 amino acid percent identity with SEQ ID NO: 2. Applicant's argument is persuasive and the requirement to elect one amino acid sequence from SEQ ID NO: 2, 3, 4, 5, 6, and 9 is withdrawn.

Claims 90 and 91 are withdrawn because the claims are drawn to the non-elected invention. Claims 49-89 including SEQ ID NO: 2, 3, 4, 5, 6, and 9 are examined on the merits.

Priority

Acknowledgment is made for priority to a CIP application, 09/719,277, which issued as a US Patent 7,052,830, which is a 371 of PCT/US99/12929, which claims benefit of 60/088,670 and 60/089138. The limitation of the SEQ ID NO: 9 is not seen in the applications of PCT/US99/12929, 60/088,670 or 60/089138. As such the claims are granted the priority date of 4/13/2001.

Information Disclosure Statement

The Information Disclosure Statements received May 20, 2005 and December 05, 2003 have been considered and attached to this Office Action.

Double Patenting Rejection

Claims 49-89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No 7,052,830 in view of Deleys et al., US Patent No 5,922,532.

Claims 49-89 are drawn to a method of diagnosing HCV infection, comprising contacting an isolated, purified, or synthetic polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ ID NO: 1 with a biological sample from a subject, and determining the presence or absence of an antibody, wherein presence of the antibody indicates infection with HCV. The polypeptides used in the currently claimed method of diagnosing HCV are SEQ ID NO: 2, 3, 4, 5, 6, and 9.

Claims 1-34 of US Patent No 7,052,830 teach a method of diagnosing HCV infection, comprising contacting a biological sample from a subject with an antibody that specifically binds to a polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ ID NO: 1, determining the presence or absence of polypeptide, wherein presence of polypeptide indicates infection with HCV. The polypeptides to be detected in a sample are SEQ ID NO: 2, 3, 4, 5, 6, and 9.

Thus, the polypeptides represented by SEQ ID NO: 2, 3, 4, 5, 6, and 9 recited in claims 1-34 of US Patent No 7,052,830, which are detected in a biological sample in a method of

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diagnosing HCV infection are identical to the polypeptides of SEQ ID NO: 2, 3, 4, 5, 6, and 9 used for detection of an antibody in a biological sample in the currently claimed method. The currently claimed method and the method taught in the US Patent No 7,052,830 are directed to diagnosing HCV infection. The difference between the two methods is that in the currently claimed method, the antibody specifically binding to SEQ ID NO: 2, 3, 4, 5, 6, and 9 is being detected in a biological sample, and in the method of the US Patent No 7,052,830 the polypeptides of SEQ ID NO: 2, 3, 4, 5, 6, and 9 are being detected in a biological sample using an antibody that specifically binds the said polypeptides.

It would have been obvious to the person of ordinary skill in the art to detect the presence of an antibody with specificity to the HCV polypeptide in a biological sample, in the method of diagnosing HCV infection, as opposed to detecting the HCV polypeptide in a biological sample using an antibody with specificity to the HCV polypeptide. One would have been motivated to detect the presence of an antibody with specificity to the HCV polypeptide in a biological sample, because Deleys et al., US Patent No 5,922,532 teaches the method of diagnosing HCV infection comprising detection of antibodies to HCV in a biological sample using polypeptides specific to the said antibodies.

One skilled in the art would have had a reasonable expectation of success to detect the presence of an antibody with specificity to the HCV polypeptide in a biological sample using peptides specifically binding the said antibodies because immunological methods such as ELISA and RIA used to detect antibodies in a biological sample are routinely performed in the art.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.
Examiner

9/7/06

Stacy B. Chen 9/11/06
STACY B. CHEN
PRIMARY EXAMINER